

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 4

#### REMARKS

Claims 1-5 are pending in the instant application. Claims 1-5 have been rejected. Claim 1 has been amended and claims 2-5 have been canceled without prejudice. Support for these amendments is provided in the specification at page 1, line 11, page 4, line 34, through page 5, line 14, and page 17, line 23, and page 18, line 5. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Information Disclosure Statement

The Examiner has indicated that references AD, AE, AQ and AS were not considered as copies were not provided by Applicant due to the voluminous nature of these standard reference texts. The Examiner has requested copies of these references be provided for examination and consideration. However, upon review of these references, Applicants believe that such references are not relevant to the novelty and/or obviousness of the claimed subject matter and therefore need not be considered by the Examiner in this case.

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 5

II. Rejection of Claims 2-5 under 35 U.S.C. § 112, first  
paragraph

Claims 2-5 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for a method of diagnosing the presence of gastrointestinal cancer in a patient comprising determining levels of a polynucleotide comprising SEQ ID NO:3 or a polynucleotide encoding a polypeptide comprising SEQ ID NO:4 in cells, tissue or bodily fluids in a patient and comparing the determined levels of a polynucleotide comprising SEQ ID NO:3 or a polynucleotide encoding a polypeptide comprising SEQ ID NO:4 in cells, tissue or bodily fluids from a normal human control, wherein a change in determined levels of a polynucleotide comprising SEQ ID NO:3 or a polynucleotide encoding a polypeptide comprising SEQ ID NO:4 in said patient versus normal human control is associated with the presence of gastrointestinal cancer. However, the Examiner suggests that the specification does not reasonably provide enablement for methods of diagnosing metastases, staging and monitoring change in gastrointestinal cancer.

Applicants respectfully disagree with the Examiner as it is routine to those of skill in the art to adapt diagnostic methods

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 6

for cancer to methods for diagnosing metastases, monitoring and staging of cancer. Accordingly, Applicants believe that the instant specification is enabling for claims 2-5.

However, in an earnest effort to advance the prosecution of this case, Applicants have canceled claims 2-5, thus mooted this rejection.

Withdrawal of this rejection is therefore respectfully requested.

**III. Rejection of Claims 1-5 under 35 U.S.C. § 112, second paragraph**

Claims 1-5 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that the phrase "hybridizes under stringent conditions" is indefinite because the claims do not set forth the conditions encompassed by this phrase necessary to implement the claimed inventions.

Applicants respectfully traverse this rejection since the conditions under which stringent hybridization occurs are well known to those skilled in the art and need not be set forth in detail in the instant specification or claims.

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 7

However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 in accordance with the Examiner's suggestion to delete this phrase and to state that levels of SEQ ID NO:3 or a polynucleotide encoding a polypeptide comprising SEQ ID NO:4 are determined in cells, tissues or bodily fluids in a patient. Support for this amendment can be found in the specification at page 4, line 34, through page 5, line 14, and page 17, line 23, and page 18, line 5.

Applicants have also amended claim 1 to be drawn to a method of detecting the presence of gastrointestinal cancer in accordance with teachings throughout the specification and in particular at page 1, line 11.

No new matter is added by these amendments.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is respectfully requested in light of this amendment.

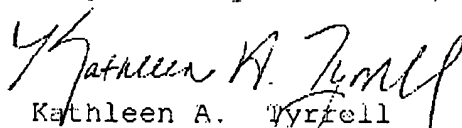
#### IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Attorney Docket No.: DEX-0142  
Inventors: Macina et al.  
Serial No.: 09/802,674  
Filing Date: March 9, 2001  
Page 8

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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